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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,996	04/20/2005	Yongren Benjamin Peng	58768.000007	8890

21967 7590 06/18/2009

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EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,996	PENG ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *21-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the restriction in the reply filed on 3/11/09 is acknowledged. The traversal is on the ground(s) that the cited references do not teach a special technical feature of the invention - a resorbable implant material comprising, *inter alia*, a resorbable base glass matrix that does not require high energy particle irradiation to convert one or more stable isotopes into radioactive isotopes. Rather, the cited references require neutron activation to convert isotopes into radioactive isotopes.

2. This is not found persuasive because the Glajch et al. reference 6,455,024B1 states that the radionuclide is distributed substantially uniformly throughout the inorganic material (i.e. amorphous or glass state) (column 3, lines 33-35; column 5, lines 13-25). Example 2 and example 4 teach of the inclusion of ^{33}P and ^{90}Sr into a glass phosphate particle, respectively, without the high energy particle irradiation (column 12, lines 8-24 and 49-50). The Glajch et al. reference 6,455,024B1 also states the radionuclide is activated by neutron bombardment prior to formation of the particle and that materials which are initially nonradioactive can be subjected to neutron irradiation, thus producing a beta-emitting radioisotope (column 4, lines 65-67 [34]; column 4, lines 5-7). Co-precipitation would be preferred for incorporation of the radionuclide as a part of the particle throughout the matrix of the particle (column 9, lines 19-33 and 56-62). The requirement is still deemed proper and is therefore made FINAL.

3. Claims 21-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups II and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/11/09.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what constitutes "***an amount effective*** for radiation synovectomy of arthritis" or "***an amount effective*** for radiation therapy of a tumor" as the specification does not provide any guidance to distinguish the amounts necessary for the two distinct treatments.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4,11 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Glajch et al. (US 6,455,024 B1).

8. Glajch et al. (US 6,455,024 B1) teaches of a particle/implant which is in a glass state and is comprised of silicas, phosphates, etc., such as calcium phosphate (column 5, lines 12-25 and 55-60) and radionuclides, such as ^{90}Y, ^{32}P, ^{33}P, ^{90}Sr (column 3, lines 22-35; column 5, lines 62+; examples 1-4). The phosphate may include a nitrogen rich layer containing up to 12 wt % nitrogen and the radionuclide may be distributed substantially uniformly throughout the inorganic material where the radionuclide of interest may be contacted with the particle via co-precipitation and therefore does not need or require high energy particle irradiation to convert one or more stable isotopes into radioactive isotopes (column 3, lines 22-35; column 4, lines 65-67; column 5, lines 45-53; column 9, lines 19-28). Co-precipitation is the process in which the radionuclide in a soluble form is intimately mixed with a soluble precursor of the inorganic material. The radionuclide and the inorganic materials are made to concurrently precipitate by means of changing the solvent, adding a precipitating solvent in which the radionuclide and inorganic materials are not soluble, etc. (column 9, lines 56-62). The particles of the disclosure are encapsulated within a biocompatible material/nonconductive delivery vehicle, such as polyethylene terephthalate (PET) and may be used for the method of treating a tumor (i.e. brachytherapy) (column 1, lines 9-16; column 4, lines 9-14 and 47-50).

9. It is respectfully pointed out that instant claims 1-4,11 and 15-20 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

10. Claims 1-3,6,7,11-13,15 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US2004/0131543A1).

11. Wong et al. (US2004/0131543A1) teaches of particles/microsphere radiopharmaceutical macroaggregates comprising a metal and one or more radioactive isotopes and which have sufficient radioactivity (p2, [0014]). The particles may be glass microspheres where the non-radioactive metal (i.e. Ca or Gd) and one or more radioactive isotopes are adsorbed by the glass material (p2-3, [0017]). The microsphere radiopharmaceutical macroaggregates are used for MRI, methods for the locoregional treatment of abnormal tissue (i.e. tumor, synovial tissue) and for acupuncture therapy of rheumatoid arthritis (p3, [0018] and [0022]; p4, [0037]; p10, [0076]; p11, [0079]). The microsphere radiopharmaceutical macroaggregates are prepared via coprecipitation of phytate (Inositol hexaphosphate) a non-radioactive cation, a radionuclide cation (^{90}Y) and a radionuclide anion (^{99m}Tc) (p6, [0053]). The

radiopharmaceutical macroaggregates have radioactivity levels of about 1 microcurie to about 500 mCi (p8, [0064]).

12. It is respectfully pointed out that instant claims 1-3,6,7,11-13,15 and 17 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-5,8,10-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glajch et al. (US 6,455,024 B1) in view of Day et al. (US 5,011,797).

15. Glajch et al. (US 6,455,024 B1) discloses a particle/implant which is in a glass state and is comprised of silicas, phosphates, etc., such as calcium phosphate (column 1, lines 8-16; column 5, lines 12-25 and 55-60) and radionuclides, such as ^{90}Y, ^{32}P, ^{33}P, ^{90}Sr (column 3, lines 22-35; column 5, lines 62+; examples 1-4). The phosphate may

include a nitrogen rich layer containing up to 12 wt % nitrogen and the radionuclide may be distributed substantially uniformly throughout the inorganic material where the radionuclide of interest may be contacted with the particle via co-precipitation and therefore does not need or require high energy particle irradiation to convert one or more stable isotopes into radioactive isotopes (column 3, lines 22-35; column 4, lines 65-67; column 9, lines 19-28). Co-precipitation is the process in which the radionuclide in a soluble form is intimately mixed with a soluble precursor of the inorganic material. The radionuclide and the inorganic materials are made to concurrently precipitate by means of changing the solvent, adding a precipitating solvent in which the radionuclide and inorganic materials are not soluble, etc. (column 9, lines 56-62). The particles/implants of the disclosure are encapsulated within a biocompatible material/nonconductive delivery vehicle, such as polyethylene terephthalate (PET) and may be used for the method of treating a tumor (i.e. brachytherapy) (column 1, lines 9-16; column 4, lines 9-14 and 47-50). The implants may be administered parenterally (column 1, lines 8-16). Glajch et al. does not disclose the total radioactivity of the isotopes or the amount used for radiation therapy of a tumor or for radiation synovectomy of arthritic joints.

16. Glajch et al. discloses that the amount of radionuclide present in terms of wt % will depend on a number of issues: radionuclide chosen, amount of radioactivity required, etc. and can be calculated to provide for the activity required to treat a given tumor volume (Glajch et al. column 6, lines 14-28). Therefore, at the time of the invention it would have been obvious to one skilled in the art to provide the

particles/implants in an amount effective of a radionuclide for radiation therapy of a tumor, such as curies of total radioactivity since Glajch et al. teaches that the particles/implants are used for the method of treating a tumor.

17. The calcium phosphate glass particles/implants of Glajch et al. encompasses the calcium phosphate resorbable implant of the disclosure and thus are capable of the same functions and have the same properties, such as calcium to phosphate ratio from about 0.33 to about 1.67.

18. Day et al. (US 5,011,797) discloses novel biodegradable and biologically compatible glass microspheres, such as lithium silicates, etc. for radiation synovectomy of arthritic joints which comprises a radionuclide, such as samarium-153 (column 1, lines 9-13; column 8, lines 25-38).

19. At the time of the invention it would have been obvious to one ordinarily skilled in the art that the silicate particles of Glajch et al. are capable of providing an amount effective of a radionuclide for radiation synovectomy of arthritis as the disclosures of Glajch et al. and Day et al. are drawn to the same utility, such as silicate glass particles comprising radionuclides.

20. It is respectfully pointed out that instant claims 1-5,8,10-16 and 18-20 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the

prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

21. Claims 1-5,8-11,13-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glajch et al. (US 6,455,024 B1) in view of Gilchrist et al. (US 6,143,318).

22. Glajch et al. (US 6,455,024 B1) discloses a particle/implant which is in a glass state and is comprised of silicas, phosphates, etc., such as calcium phosphate (column 5, lines 12-25 and 55-60) and radionuclides, such as ^{90}Y, ^{32}P, ^{33}P, ^{90}Sr as well as that stated above. Glajch et al. does not disclose the inclusion of selenium.

23. Gilchrist et al. (US 6,143,318) discloses that soluble phosphate glasses are biocompatible and can incorporate inorganic metals such that a sustained release of the metals can be provided at a wound site (column 1, lines 25-37) or that selenium may be included into controlled release glasses to provide a bactericidal benefit to promote wound healing (abstract; column 1, lines 46-63).

24. At the time of the invention it would have been obvious to one skilled in the art to include selenium in a glass phosphate implant, such as that of Glajch et al. to provide a bactericidal benefit at the implantation site of the particles/implants of Glajch et al. as both disclosures are drawn to the same utility, such as biocompatible resorbable phosphate glass implants.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618